Alkermes Initiates Clinical Study of ALKS 5461 for Treatment-Resistant Depression

June 15, 2011

WALTHAM, Mass., Jun 15, 2011 (BUSINESS WIRE) -- Alkermes, Inc. (NASDAQ: ALKS) today announced the initiation of a phase 1/2 study of ALKS 5461 for treatment-resistant depression (TRD). ALKS 5461 is the combination of ALKS 33, a proprietary opioid modulator, and buprenorphine. TRD, which is also known as refractory depression, refers to depressive episodes that are not adequately controlled by standard antidepressant therapy. The multicenter, randomized, double-blind, placebo-controlled trial is designed to assess the safety and potential efficacy of ALKS 5461 in subjects with TRD. Alkermes expects to provide topline results from this study in the second half of calendar 2011.

"Many patients with depression do not adequately respond to existing pharmacological therapies, underscoring the unmet need for this serious and chronic disease," stated Elliot Ehrich, Chief Medical Officer of Alkermes. "The combination of ALKS 33 with buprenorphine to create ALKS 5461 leverages our expertise with opioid modulators and may create a non-addictive therapy for treatment-resistant depression."

The phase 1/2, multicenter, randomized, double-blind, placebo-controlled, parallel-group, multi-dose study is designed to evaluate the safety and tolerability of ALKS 5461 in 32 patients with major depressive disorder who had shown an inadequate response to previous antidepressant therapy. Two different ratios of the components will be given in an escalating dose titration once daily for seven days via sublingual administration. The pharmacokinetics and efficacy of ALKS 5461 will also be evaluated.

ALKS 5461 is designed to be a non-addictive, kappa antagonist for the treatment of TRD. Preclinical research has demonstrated that kappa blockade has antidepressant effects in behavioral models of depression. Both components of ALKS 5461 have established activity at mu opioid receptors, with ALKS 33 functioning as an antagonist of the mu receptor and buprenorphine as a partial agonist. The net effect of this combination may attenuate buprenorphine's mu agonist effects, therefore making it potentially non-addictive.

About ALKS 5461

ALKS 5461 is the combination of ALKS 33 and buprenorphine. ALKS 33 is an oral opioid modulator that builds on Alkermes' scientific expertise in opioid biology and pharmacology, as well as the company's clinical and commercial knowledge in the field of addiction and central nervous system disorders. Clinical studies of ALKS 33 in over 400 patients to date have shown that it is generally well tolerated with a duration of action consistent with once-daily dosing. ALKS 5461 is also in clinical development for the treatment of cocaine addiction, which is being funded through a grant from the National Institute on Drug Abuse (NIDA).

About Depression and TRD

Depression is a serious and chronic disease that affects more than 20 million American adults each year,[1] and finding the right treatment can be difficult for many patients. Approximately half of depressed patients have an inadequate response to monotherapy,[2] and as many as 20% have chronic depression despite multiple interventions.[3] TRD is diagnosed when a patient has an inadequate response to trials of two or more antidepressant therapies.

About Alkermes

Alkermes, Inc. is a fully integrated biotechnology company committed to developing innovative medicines to improve patients' lives. Alkermes developed, manufactures and commercializes VIVITROL® for alcohol and opioid dependence and manufactures RISPERDAL® CONSTA® for schizophrenia and bipolar I disorder. Alkermes' robust pipeline includes extended-release injectable and oral products for the treatment of prevalent, chronic diseases, such as central nervous system disorders, addiction and diabetes. Headquartered in Waltham, Massachusetts, Alkermes has a research facility in Massachusetts and a commercial manufacturing facility in Ohio. For more information, please visit Alkermes' website at www.alkermes.com.

Note Regarding Forward-Looking Statements

Certain statements set forth in this press release constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, including, but not limited to: statements concerning the planned future development of ALKS 5461, including the expected timing of the clinical trial and the date by when topline results from the study will be available; and the therapeutic value of the company's products. You are cautioned that forward-looking statements are inherently uncertain. Although the company believes that such statements are based on reasonable assumptions within the bounds of its knowledge of its business and operations, the forward-looking statements are neither promises nor guarantees and they are necessarily subject to a high degree of uncertainty and risk. Actual performance and results may differ materially from those projected or suggested in the forward-looking statements due to various risks and uncertainties. These risks and uncertainties include, among others: whether preclinical and early clinical results for ALKS 33, alone and in combination with buprenorphine, will be predictive of future clinical study results; whether future clinical trials for ALKS 5461 will be completed on time or at all; whether there will occur potential changes in cost, scope and duration of the ALKS 5461 clinical trial; whether ALKS 5461 could be shown ineffective or unsafe during clinical studies, and we may not be permitted by regulatory authorities to undertake new or additional clinical studies for ALKS 5461; and those risks described in Part 1, Item 1A, "Risk Factors" of our Annual Report on Form 10-K for the year ended March 31, 2011. The information contained in this press release is provided by the company as of the date hereof, and, except as required by law, the company disclaims any intention or responsibility for updating any forward-looking information contained in this press release.

[1] Kessler RC, Chiu WT, Demler O, Walters EE. Prevalence, severity, and comorbidity of twelve-month DSM-IV disorders in the National Comorbidity Survey Replication (NCS-R). *Archives of General Psychiatry*, 2005 Jun; 62 (6): 617-27.

[2] Bauer M, Whybrow PC, Angst J, et al. World Federation of Societies of Biological Psychiatry (WFSBP) Guidelines for Biological Treatment of Unipolar Depressive Disorders, Part 1: Acute and continuation treatment of major depressive disorder. *World J Biol Psychiatry,* 2002; 3:5-43.

[3] Paykel ES. Epidemiology of refractory depression. In: Nolen WA, Zohar J, Roose SP, et al, editors. Refractory depression: current strategies and future directions. New York: Wiley; 1994:3-18.

SOURCE: Alkermes, Inc.

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